

## CLAIMS

What we claim is:

- 1     1.     A catheter system for use in forming a pathway between an extraluminal space  
2     within a blood vessel and a true lumen of the blood vessel, comprising:  
3         a catheter body including at least one lumen configured to track over a guide wire  
4     to a treatment site;  
5         a catheter endpiece coupled to the distal end of the catheter body, the catheter  
6     endpiece including at least one port in communication with the lumen; and  
7         a working element having a distal end configured to deploy through the port for  
8     delivery from a first vascular location within the extraluminal space to a second vascular  
9     location within the true lumen of the blood vessel when the working element is advanced  
10    distally through the port, wherein a distal end of the catheter body assumes one of a first  
11    and a second configuration when the working element is proximally retracted into the  
12    catheter body.
- 1     2.     The catheter system of claim 1, wherein the first configuration is a straight  
2     configuration.
- 1     3.     The catheter system of claim 1, wherein the second configuration is a curved  
2     configuration.
- 1     4.     The catheter system of claim 1, wherein an inside diameter of the lumen is  
2     uniform.
- 1     5.     The catheter system of claim 1, wherein the working element includes a cannula  
2     having at least one lumen.
- 1     6.     The catheter system of claim 5, wherein the cannula includes braided tubular  
2     composition.

1 7. The catheter system of claim 1, wherein the working element includes at least one  
2 guide wire.

1 8. The catheter system of claim 1, wherein the working element includes a cannula  
2 and at least one guide wire, wherein the guide wire is slidably disposed within the  
3 cannula.

1 9. The catheter system of claim 1, wherein the working element includes a  
2 sharpened distal tip.

1 10. The catheter system of claim 1, wherein the port is positioned at a distal end of  
2 the catheter endpiece.

1 11. The catheter system of claim 1, wherein the port is positioned proximal to a distal  
2 end of the catheter endpiece.

1 12. The catheter system of claim 1, wherein the at least one port includes a first port  
2 positioned at a distal end of the catheter endpiece, and a second port positioned in at least  
3 one region proximal to the distal end of the catheter endpiece.

1 13. The catheter system of claim 1, wherein the distal end of the working element  
2 includes a preformed resilient tip.

1 14. The catheter system of claim 1, further comprising at least one guide wire.

1 15. The catheter system of claim 1, further comprising at least one component of an  
2 active visualization system.

1 16. The catheter system of claim 1, further comprising at least one component of a  
2 passive visualization system.

- 1 17. The catheter system of claim 16, wherein the component includes at least one  
2 component of a fluoroscopic marking system positioned on the catheter body.
- 1 18. The catheter system of claim 16, wherein the component includes at least one  
2 component of a fluoroscopic marking system positioned on the working element.
- 1 19. The catheter system of claim 1, further comprising a deflection mechanism in  
2 communication with the lumen and the port.
- 1 20. The catheter system of claim 1, wherein the extraluminal space is located within  
2 diffuse disease of the blood vessel.
- 1 21. The catheter system of claim 1, wherein the extraluminal space is located between  
2 an adventitial layer and an intimal layer of the blood vessel.
- 1 22. The catheter system of claim 1, wherein the catheter body includes a tubular wire  
2 braid laminated with polymer.
- 1 23. The catheter system of claim 22, wherein the catheter shaft is terminated with at  
2 least one internal ring and at least one external ring, wherein the internal ring is  
3 connected to an internal surface of the tubular wire braid and the external ring is  
4 connected to an external surface of the tubular wire braid.
- 1 24. The catheter system of claim 23, wherein a proximal internal surface of the  
2 external ring is internally tapered so that polymer of the catheter body continues into the  
3 taper.
- 1 25. The catheter system of claim 1, wherein the working element is connected to a  
2 linear slide mechanism in a proximal handle.

1 26. The catheter system of claim 25, wherein the slide mechanism locks when fully  
2 retracted and prevents inadvertent actuation of the working element.

1 27. A re-entry catheter for use in forming a pathway between an extraluminal space  
2 within a blood vessel and a true lumen of the blood vessel, comprising:  
3 a catheter body including at least one lumen configured to track over a guide wire  
4 to a treatment site;  
5 a catheter endpiece coupled to the distal end of the catheter body, the catheter  
6 endpiece including at least one port in communication with the lumen, and  
7 a working element having a distal end configured to deploy through the port for  
8 delivery from a first vascular location within the extraluminal space to a second vascular  
9 location within the true lumen of the blood vessel when the working element is advanced  
10 distally through the port, wherein a distal end of the catheter body assumes a curved  
11 configuration when the working element is proximally retracted into the catheter body.

1 28. A re-entry catheter for use in forming a pathway between an extraluminal space  
2 within a blood vessel and a true lumen of the blood vessel, comprising:  
3 a catheter body including at least one lumen configured to track over a guide wire  
4 to a treatment site;  
5 a catheter endpiece coupled to the distal end of the catheter body, the catheter  
6 endpiece including at least one port in communication with the lumen, and  
7 a working element having a distal end configured to deploy through the port for  
8 delivery from a first vascular location within the extraluminal space to a second vascular  
9 location within the true lumen of the blood vessel when the working element is advanced  
10 distally through the port, wherein a distal end of the catheter body assumes a straight  
11 configuration when the working element is proximally retracted into the catheter body.

1 29. A catheter system for use in forming a pathway between an extraluminal space  
2 within a blood vessel and a lumen of the blood vessel, comprising:

3 a catheter body configured for advancement over a wire into the extraluminal  
4 space to a re-entry target location of the blood vessel lumen, the catheter body including  
5 at least one distal port and at least one lumen;

6 a cannula selectively disposed within the at least one lumen and configured for  
7 slidable deployment from the distal port of the catheter for use in generating a passage  
8 from the extraluminal space into the blood vessel lumen;

9 an active visualization device configured for deployment to a distal region of the  
10 catheter system via at least one of the lumen and the cannula for generating images for  
11 use in positioning at least one of the cannula and the distal port of the catheter body  
12 relative to the re-entry target location; and

13 a guide wire positioned in at least one of the catheter body lumen and the cannula  
14 and configured for advancement into the blood vessel lumen via the passage.

1 30. The catheter system of claim 29, wherein a distal end of the catheter body  
2 assumes one of a first and a second configuration when the cannula is proximally  
3 retracted into the catheter body.

1 31. The catheter system of claim 30, wherein the first configuration is a straight  
2 configuration.

1 32. The catheter system of claim 30, wherein the second configuration is a curved  
2 configuration.

1 33. The catheter system of claim 29, wherein an inside diameter of the lumen is  
2 uniform.

1 34. The catheter system of claim 29, wherein the cannula includes a sharpened distal  
2 tip.

1 35. The catheter system of claim 29, wherein the distal port is positioned at a distal  
2 end of the catheter body.

1 36. The catheter system of claim 29, wherein the distal port is positioned proximal to  
2 a distal end of the catheter body.

1 37. The catheter system of claim 29, wherein the at least one distal port includes a  
2 first port positioned at a distal end of the catheter body, and a second port positioned in at  
3 least one region proximal to the distal end of the catheter body.

1 38. The catheter system of claim 29, wherein a distal end of the cannula includes a  
2 preformed resilient tip.

1 39. The catheter system of claim 29, further comprising at least one component of a  
2 passive visualization system.

1 40. The catheter system of claim 39, wherein the component of a passive  
2 visualization system includes at least one component of a fluoroscopic marking system  
3 positioned on the catheter body.

1 41. The catheter system of claim 39, wherein the component of a passive  
2 visualization system includes at least one component of a fluoroscopic marking system  
3 positioned on the cannula.

1 42. The catheter system of claim 29, further comprising a deflection mechanism in  
2 communication with the catheter body lumen and the distal port.

1 43. The catheter system of claim 29, wherein the extraluminal space is located within  
2 diffuse disease of the blood vessel.

1 44. The catheter system of claim 29, wherein the extraluminal space is located  
2 between an adventitial layer and an intimal layer of the blood vessel.

1 45. The catheter system of claim 29, wherein the images include images of vascular  
2 tissue surrounding a distal end of the catheter body.

1 46. The catheter system of claim 29, wherein the active visualization device includes  
2 at least one of a rotational imaging device, an ultrasonic imaging device, an optical  
3 coherence tomography device, and a phased array imaging device.

1 47. The catheter system of claim 29, wherein the active visualization device is  
2 configured for delivery via a lumen of the cannula to a distal end of the catheter body.

1 48. The catheter system of claim 29, wherein the active visualization device is  
2 configured for delivery via a lumen of the catheter to a distal end of the catheter body.

1 49. The catheter system of claim 29, wherein the cannula includes at least one feature  
2 that is identifiable using the active visualization device and is in registration with a  
3 deployment direction of the cannula from the distal port.

1 50. The catheter system of claim 29, wherein a distal region of the catheter body  
2 includes at least one feature that is identifiable using the active visualization device and is  
3 in registration with a deployment direction of the cannula from the distal port.

1 51. The catheter system of claim 29, wherein the catheter body and the cannula are  
2 keyed together.

1 52. A catheter system for use in forming a pathway between an extraluminal space  
2 within a blood vessel and a lumen of the blood vessel, comprising:  
3 a catheter body configured for advancement over a wire into the extraluminal  
4 space to a re-entry target location of the blood vessel lumen, the catheter body including  
5 at least one distal port and at least one lumen;

6 a cannula selectively disposed within the at least one lumen and configured for  
7 slidable deployment from the distal port of the catheter for use in generating a passage  
8 from the extraluminal space into the blood vessel lumen;

9 an active visualization device on at least one distal end region of the catheter  
10 body, wherein the active visualization device generates images for use in positioning at  
11 least one of the cannula and the distal port of the catheter body relative to the re-entry  
12 target location; and

13 a guide wire positioned in at least one of the catheter body lumen and the cannula  
14 and configured for advancement into the blood vessel lumen via the passage.

1 53. A catheter system for use in forming a pathway between an extraluminal space  
2 within a blood vessel and a lumen of the blood vessel, comprising:

3 means for forming a track from the blood vessel lumen into an extraluminal space  
4 between an intimal layer and an adventitial layer of the blood vessel, wherein the track  
5 extends from proximal of an occlusion in the blood vessel to a point distal to the  
6 occlusion; and

7 means for selectively forming a passage from the track back into the blood vessel  
8 lumen at a re-entry location distal to the occlusion via at least one port of a catheter  
9 system.

1 54. The catheter system of claim 53, further comprising means for identifying the re-  
2 entry location.

1 55. The catheter system of claim 53, wherein the means for selectively forming a  
2 passage further includes means for selectively deploying a working element from a distal  
3 region of the catheter system.

1 56. The catheter system of claim 53, wherein the means for selectively forming a  
2 passage further includes means for selectively aligning a working element of the catheter  
3 system with the re-entry location.



1 57. The catheter system of claim 53, further comprising means for tracking the  
2 catheter system to a site proximate to the occlusion.

1 58. A catheter system for use in forming a passage between an extraluminal space  
2 within tissue of a blood vessel and a true lumen of the blood vessel, comprising:  
3 means for advancing the catheter system into the extraluminal space at a location  
4 proximal to an occlusion in the blood vessel;  
5 means for positioning a working element in the catheter system;  
6 means for identifying a location for re-entering the blood vessel lumen from the  
7 extraluminal space, wherein the re-entry location is distal to the occlusion;  
8 means for positioning at least one port of the catheter system towards the re-entry  
9 location; and  
10 means for selectively forming a passage from the extraluminal space back into the  
11 blood vessel lumen at the re-entry location via the port.